

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: PAUL D. YASGER
ABBOTT LABORATORIES
CHAD 0377/AP6D-2
100 ABBOTT PARK ROAD
ABBOTT PARK IL 60064-6050

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing
(day/month/year)

13 SEP 2000

Applicant's or agent's file reference
6416.PC.01

REPLY DUE

within **ONE** months
from the above date of mailing

International application No.
PCT/US99/23622

International filing date (day/month/year)
12 OCTOBER 1999

Priority date (day/month/year)
14 OCTOBER 1998

International Patent Classification (IPC) or both national classification and IPC
Please See Supplemental Sheet.

Applicant
ABBOTT LABORATORIES

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 14 FEBRUARY 2001

Name and mailing address of the IPEA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

PATRICIA K. BEX

Telephone No. (703) 308-0661

DEBORAH THOMAS
PARALEGAL SPECIALIST

I. Basis of the opinion**1. With regard to the elements of the international application:***☒ the international application as originally filed☒ the description:

pages 1-47

pages NONE

pages NONE

, as originally filed
, filed with the demand
, filed with the letter of☒ the claims:

pages 48-53

pages NONE

pages NONE

pages NONE

, as originally filed
, as amended (together with any statement) under Article 19
, filed with the demand
, filed with the letter of☒ the drawings:

pages 1-29

pages NONE

pages NONE

, as originally filed
, filed with the demand
, filed with the letter of☒ the sequence listing part of the description:

pages NONE

pages NONE

pages NONE

, as originally filed
, filed with the demand
, filed with the letter of**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:**☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.**4. ☒ The amendments have resulted in the cancellation of:**☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/fig NONE**5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement****Novelty (N)**

Claims	<u>8-11, 18, 21</u>	YES
Claims	<u>1-7, 12-17, 19-20</u>	NO

Inventive Step (IS)

Claims	<u>8-11, 18, 21</u>	YES
Claims	<u>1-7, 12-17, 19-20</u>	NO

Industrial Applicability (IA)

Claims	<u>1-21</u>	YES
Claims	<u>NONE</u>	NO

2. citations and explanations

Claims 1-7, 12-17, 19-20 lack novelty under PCT Article 33(2) as being anticipated by Thorne et al. (USP 4,678,752).

Thorne et al teaches a method of performing a determination of an item of interest in an automatic analyzer 12, by providing a first container 40 for processing a sample comprising the item of interest, transferring the sample to the first container in a first process path, adding a reagent to the first container in the first process path, mixing the contents of the first container in the first process path, separating the item of interest in the sample from the contents of the first container, transferring the separated item of interest to a second container 38 in a second process paths 59, 18 within the analyzer, bringing the contents of the second container to a first temperature different from the temperature of the first process path in the second process path by incubation means 18, detecting the item of interest in the second container in the second process path by detector 19 (columns 4-11, Fig. 1).

The sealing means 24, 46 is taught at Fig. 2.

Claims 8-11, 18, 21 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method wherein the second process path includes a plurality of second process sub-paths, and wherein the transferring step comprises transferring the second container to at least one of the plurality of second process sub-paths.

Claims 1-21 meet the criteria of PCT Article 33(4) because a method of performing a determination of an item of interest has industrial applicability.

----- NEW CITATIONS -----

US 4,678,752 A (THORNE et al) 07 JULY 1987, see columns 4-11.

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VI. Certain documents cited

1. Certain published documents (Rule 70.10)

<u>Application No. Patent No.</u>	<u>Publication Date (day/month/year)</u>	<u>Filing Date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
US 5,885,529	23 MARCH 1999	28 JUNE 1996	

2. Non-written disclosures (Rule 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>

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VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 22 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claim is indefinite for the following reason(s): The claim lacks a body, it discloses only the preamble. Further, pages 54-55 are missing from the application.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7): GO1N 35/02 and US Cl.: 436/43, 47, 48, 49, 164, 172; 422/63, 64, 65, 68.1, 81, 82.05, 82.08, 100 ; 435/ 287.1, 287.2, 287.3, 288.7